APR - 8 2008

510(k) SUMMARY

K073492

1. DATE PREPARED

December 12, 2007

2. SPONSOR INFORMATION

Address

TYSON BIORESEARCH, INC.
5 F., # 22, KE TUNG RD., SCIENCE BASED INDUSTRIAL PARK
CHUN-NAN, MIAO-LI COUNTY, CHINA (TAIWAN) 350

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3. NAME OF DEVICE:

Trade Name:	DIACHEX+ DETERMINE Blood Glucose Monitoring System DIACHEX+ INFINITY Blood Glucose Monitoring System
Common Names/Descriptions:	Blood Glucose Monitoring System
Classification Names:	Glucose test system, product code 75CGA and "System, test, blood glucose, over the counter", product code 75NBW, 21 CFR 862.1345

4. DEVICE DESCRIPTION:

The DIACHEX+ DETERMINE / DIACHEX+ INFINITY Blood Glucose Monitoring System designed by Tyson Bioresearch Inc., an amperometric biosensor, is adopted for its ease of use, its ability to process accurate results utilizing only a small volume of blood, and its quick response time. DIACHEX+ DETERMINE / DIACHEX+ INFINITY provide a convenient and safe monitoring system for diabetes health care professionals, hospitals and most importantly, people with diabetes.

The DIACHEX+ DETERMINE / DIACHEX+ INFINITY Blood Glucose Monitoring System is intended for use in the quantitatively measurement of glucose (sugar) in fresh capillary whole blood from the fingertip and the alternative sites: the palm and the forearm. The DIACHEX+ DETERMINE / DIACHEX+ INFINITY Blood Glucose

Test Strips are for testing outside the body (in vitro diagnostic use). When the edge of the test strip is touched to a drop of blood, the test strip draws the blood into the sample chamber and the glucose reading is displayed on the meter after 10 seconds. The test measures glucose from 20 mg/dL (1.1mmol/L) to 600 mg/dL (33.3 mmol/L). The test strip is calibrated to display the equivalent of plasma glucose values to allow the comparison of results with laboratory methods.

5. INTENDED USE:

The DIACHEX$^+$ DETERMINE / DIACHEX$^+$ INFINITY Blood Glucose Monitoring System is intended for use in the quantitatively measurement of glucose (sugar) in fresh capillary whole blood from the fingertip and the alternative sites: the palm and the forearm. The DIACHEX$^+$ DETERMINE / DIACHEX$^+$ INFINITY Blood Glucose Test Strips are for testing outside the body (in vitro diagnostic use). The DIACHEX$^+$ DETERMINE / DIACHEX$^+$ INFINITY Blood Glucose Monitoring System is intended for use at home (over the counter [OTC]) by persons with diabetes, or in clinical setting by healthcare professionals as an aid in monitoring the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus. The alternative site testing in the systems can be used only during steady-state blood glucose conditions.

6. TEST PRINCIPLE

The test principle is based on electrochemical biosensor technology using glucose oxidase. Glucose is oxidized to gluconic acid and electrons are produced from the reaction. The electrons are then trapped by a chemical mediator, potassium ferricyanide. Once the enzymatic reaction is complete, a potential is provided by the meter for a further electrochemical reaction in order to generate a current from the release of trapped electrons. This current is then measured and correlated to the glucose concentration in the whole-blood sample. The test strip is calibrated to display the equivalent of plasma glucose values to allow easy comparison of results with laboratory methods.

7. PREDICATE DEVICE:

Predicate device name(s): DIACHEX Blood Glucose Monitoring System

Predicate 510(k) number(s): k062829

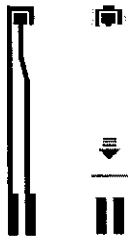
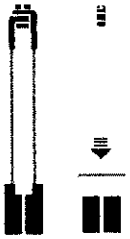
Comparison with predicate:
This 510(K) amendment addresses the modification of the DIACHEX Blood Glucose

Monitoring System previously cleared under K062829 and addition of alternate site testing sites for the glucose testing portion.

The modifications encompass the sample volume, reaction time, operating principle, meter software, LCD display and addition of alternate site testing sites (the palm and the forearm) for the glucose testing portion. The DIACHEX$^+$ Blood Glucose Monitoring System includes two models, DIACHEX$^+$ DETERMINE and DIACHEX$^+$ INFINITY. The differences between these two models are the strip ejector function, coding method, LCD display, strip width and meter outside looking. The strip of the DIACHEX$^+$ INFINITY system can be removed by pushing strip eject button and also can be removed by hand. The DIACHEX$^+$ INFINITY system eliminate the need for manual coding of the test strips by the user by assigning codes when manufactured. Except these, all main meter internal electronic components, meter functions and detection algorithm of these two models are exactly the same. The deference between DIACHEX$^+$ DETERMINE and DIACHEX$^+$ INFINITY from DIACHEX system is outline below.

Differences:

Item	Predicate Device	Proposed Device	
	DIACHEX (K062829)	DIACHEX$^+$ DETERMINE	DIACHEX$^+$ INFINITY
Blood Sample	Fingertip	Fingertip, Palm and Forearm	Fingertip, Palm and Forearm
Sample Volume	1.5uL	0.5uL	0.5uL
Test Time	10 seconds	5 seconds	5 seconds
Reminder alarm	not present	4 user setting alarms	4 user setting alarms
Hypoglycemic and hyperglycemic alarm	not present	2 user setting alarms	2 user setting alarms
LCD Display	------	Increase alarm, strip , code and control solution icons	Increase alarm, strip eject indicate and control solution icons
Average result	14 Days	7,14 and 30 Days	7,14 and 30 Days
Coding	Glucode Chip	Glucode Chip	No coding required (assign code when manufactured)
PC download option	not present	RS232	RS232

Shape of the electrode on the test strip			
Strip Eject Button	not present	not present	One eject button
Meter Size	102 x 52 x 17 (mm)	102 x 52 x 17 (mm)	92 x 58 x 19 (mm)
Meter Weight	Appx. 55 grams	Appx. 55 grams	Appx. 60 grams
Meter Connector width	5.2 mm	5.2 mm	7.2 mm

Similarities:

Item	Predicate Device	Proposed Device
	DIACHEX (K062829)	DIACHEX$^+$ DETERMINE DIACHEX$^+$ INFINITY
Test Principle	Electrochemical biosensor with glucose oxidase.	identical
Detecting Range	20 ~ 600 mg/dL	identical
Unit of measurement	mg/dL or mmol/L	identical
HCT Range	35 ~55 %	identical
Control Solution	3 Levels available	identical
Operating Temperature	10 to 40 ℃ (50-104℉)	identical
Operating Humidity	10 to 90%	identical
Memory capacity	300 Test Results	identical
Strip Storage Temperature	4 to 30 ℃ (40-86℉)	identical
Battery Power	One 3 V Lithium CR 2032 battery	identical

8. PERFORMANCE CHARACTERISTIC SUMMARY

Day to day precision of the DIACHEX+ system was performed with 3 levels of glucose control solutions each with 3 different lots test strips. Samples were tested with 10 measurements obtained from 10 meters with each level of control solution over 10 days. Within day precision test was performed with 5 levels of spiked whole blood. Samples were test with 10 measurements obtained from 10 meters with each level of blood sample using 3 different lots test strips. Results are summarized below.

Day to Day precision result

Device		Level 1	Level 2	Level 3
DIACHEX + DETERMINE	MEAN	38.6	111.4	401.8
	SD	1.81	3.05	6.87
	CV%	4.69	2.74	1.71
DIACHEX+ INFINITY	MEAN	37.7	109.4	401.3
	SD	1.77	2.86	6.64
	CV%	4.68	2.62	1.65

3 lot average results. 10 Tests of each level of each lot for 10 days.

Within Day precision result

Device	YSI	AVG	Bias %	Std	CV
DIACHEX + DETERMINE	37.7	39	4.22	1.83	4.66
	90.0	89	-1.33	2.82	3.19
	130	125	-3.67	4.10	3.29
	224	221	-1.26	5.38	2.44
	353	359	1.78	7.56	2.11
DIACHEX+ INFINITY	40.4	40	-2.29	1.89	4.78
	85.8	85	-1.42	2.83	3.35
	129	128	-0.95	4.03	3.15
	223	221	-0.98	5.64	2.56
	357	358	0.16	7.51	2.10

3 lot average results. 100 Tests of each level of each lot.

To establish the linearity of the DIACHEX+ system whole blood samples were compared to YSI 2300 with 3 lots of test strips using 10 different glucose concentrations. For each lot of test strips, 10meters were tested for each concentration. Linear regression yields the following result. The operating range of the meter is 20-600mg/dL.

	DIACHEX+ DETERMINE			DIACHEX+ INFINITY		
	LOT 1	LOT 2	LOT 3	LOT 1	LOT 2	LOT 3
Slope	1.02	1.00	1.02	1.01	1.00	1.01
Intercept	-3.31	-2.24	-1.37	-1.79	-1.23	-1.51
R2	0.9996	0.9997	0.9997	0.9999	0.9997	0.9997

The hematocrit effect of the DIACHEX+ system was evaluated of hematocrit levels 29%-59% on whole blood samples spiked with 11 hematocrit levels for 4 glucose values (44-372mg/dL). The test results were compared with the glucose values from YSI 2300. The acceptable criteria of bias was ± 10mg/dL when glucose concentration was < 75mg/dL and ± 10% for glucose concentration ≧ 75mg/dL.The result is summarized below.

HT \ YSI	Slope	Intercept	R2
29%	1.15	2.1	0.9998
32%	1.12	-2.0	0.9992
35%	1.08	-1.6	0.9999
38%	1.07	-3.9	1.0000
41%	1.04	-1.2	1.0000
44%	0.98	3.4	1.0000
47%	0.97	2.1	0.9998
50%	0.96	2.3	1.0000
53%	0.93	1.4	0.9993
56%	0.92	0.6	0.9998
59%	0.83	3.7	0.9987

Altitude study was performed with capillary whole blood samples from 20 volunteers and 5 levels spiked venous blood samples. All the results show that Bias% result is within the acceptable criteria (±10mg/dL when glucose concentration was < 75mg/dL and ± 15% for glucose concentration ≧ 75mg/dL) at altitude up to 7545 feet.

Interference was studied of the following substances with 2 levels spiked venous blood. No interference was identified as having a percent bias ≦ 10%.

Interferent	Therapeutic Test Level (mg/dL)	High Test Level (mg/dL)	No Interference Level (mg/dL)
Acetaminophen	2	4	3
Ascorbic acid	2	15	7.5
Bilirubin	1.2	20	20
Cholesterol	30	500	375

Creatinine	1.5	30	30
EDTA	---	4	4
Galactose	---	20	20
Glycerol	---	9.21	9.21
Heparin	---	60	60
Ibuprofen	4.2	40	40
L-Dopa	0.3	2	1
Maltose	---	40	40
Salicylate	30	125	125
Sodium Fluoride	---	500	500
Tetracycline	0.4	4	4
Tolazamide	2.5	5	3.75
Tolbutamide	10	100	100
Triglyceride	190	2000	2000
Uric acid	7.7	20	15

Clinical Accuracy of the DIACHEX$^+$ Blood Glucose Monitoring System

To ensure that these meters perform similarly, DIACHEX(predicate device), DIACHEX$^+$ DETERMINE and DIACHEX$^+$ INFINITY meters were compared against standard YSI-2300 by testing from the fingertip. The test was assessed in an in-house study performing by technician. 118 participants both males and females ranged from age. The samples ranged from 25.4 to 571mg/dL and hematocrit ranged from 34% to 51%.

Values obtained from meters were compared to YSI results; linear results regression analysis yielded the following results:

Fingertip	Predicate Device	Proposed Devices	
	DIACHEX	DIACHEX$^+$ DETERMINE	DIACHEX$^+$ INFINITY
N	118	118	118
Slope	0.98	0.98	0.98
Intercept	0.62	-0.32	1.31
R2	0.9843	0.9867	0.9879

The samples that met the ISO 15197 requirement were summarized below.

Device	DIACHEX	DETERMINE	INFINITY
Percentage met ISO requirement	98.3%	99.2%	99.2%
	(116 / 118)	(117 / 118)	(117 / 118)

Clinical Accuracy of the DIACHEX+ system was performed with a total of 112 lay users and 12 contrived samples (That were 33 to 48mg/dL and 462 to 581mg/dL) at 2 clinical sites and one OTC site. Participants ranged from age, education and consisted of 41% males and 59% females with sample range 33~581mg/dL and hematocrit range 33%~54%. The performance of alternate site testing (AST) of systems were also been evaluated. The test results of capillary blood obtained from fingertip was compared to the results obtained from palm and forearm. Values obtained from meters were compared to YSI results; linear result regression analysis yielded the following results.

Finger	Lay User vs YSI	Technician vs YSI	Lay User vs Technician
N	112	124	112
Slope	0.98	0.97	1.00
Intercept	-0.52	1.31	-0.62
R2	0.9789	0.9872	0.9900

The regression of AST test results was shown as below:

Lay User	Finger vs YSI	Palm vs YSI	Palm vs Finger	Forearm vs YSI	Forearm vs Finger
N	112	111	111	111	111
Slope	0.98	0.96	0.97	0.95	0.96
Intercept	-0.52	1.77	3.12	2.34	3.54
R2	0.9789	0.9796	0.9861	0.9745	0.9825

The acceptable criteria is the ISO 15197 requirement of 95% of individual glucose results falling within ±15mg/dL at glucose concentration for samples <75mg/dL and within ±20% at glucose concentrations ≧ 75mg/dL. The samples that met the ISO 15197 requirement were summarized in the table below.

Operator	Technician	Lay user		
Site	Finger	Finger	Palm	Forearm
N	124	112	111	111
Percentage met ISO requirement	100.0%	98.2%	99.1%	97.30%
	(124/ 124)	(110 / 112)	(110 / 111)	108 / 111

From the above it is concluded that the results obtained from the alternate site sampling using DIACHEX+ DETERMINE system, are similar to those obtained from finger stick whole blood with no effect on clinical action.

From the above test results, we conclude that the modification of the DIACHEX Meter

do not affect the effectiveness and safety of the device. The proposed device (DIACHEX$^+$ DETERMINE / DIACHEX$^+$ INFINITY Blood Glucose Monitoring System) is substantial equivalent to the original cleared device. The results of clinical alternate site testing demonstrate that the results obtained from the alternate site sampling are similar to those obtained from finger stick whole blood with no effect on clinical action. DIACHEX$^+$ DETERMINE / DIACHEX$^+$ INFINITY system provides the users an option to use the palm and the forearm in addition to the fingertip to collect capillary blood for self monitoring of blood glucose within certain conditions as explained in product user's manual. DIACHEX$^+$ DETERMINE / DIACHEX$^+$ INFINITY are suitable for its intended use. The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Tyson Bioresearch, Inc.
c/o Mr. Simon Tsai (Wen-Hai Tsai)
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Science-Based Industrial Park
Chu-Nan, Taiwan
Republic of China, Postal Code: 350

MAY 29 2008

Re: k073492
Trade Name: Diachex+ Determine Blood Glucose Monitoring System
Diachex+ Infinity Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, CGA
Dated: March 10, 2008
Received: March 11, 2008

Dear Mr. Tsai:

This letter corrects our substantial equivalent letter of April 8, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Indication for Use

510(k) Number (if known): K073492

Device Name: DIACHEX+ DETERMINE / DIACHEX+ INFINITY
Blood Glucose Monitoring System

Indication For Use:

The DIACHEX+ DETERMINE / DIACHEX+ INFINITY Blood Glucose Monitoring System is intended for use in the quantitatively measurement of glucose (sugar) in fresh capillary whole blood from the fingertip and the alternative sites: the palm and the forearm. The DIACHEX+ DETERMINE / DIACHEX+ INFINITY Blood Glucose Test Strips are for testing outside the body (in vitro diagnostic use). The DIACHEX+ DETERMINE / DIACHEX+ INFINITY Blood Glucose Monitoring System is intended for use at home (over the counter [OTC]) by persons with diabetes, or in clinical setting by healthcare professionals as an aid in monitoring the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus. The alternative site testing in the systems can be used only during steady-state blood glucose conditions. It is not intended for neonatal testing.

Prescription Use ____X____ (21 CFR Part 801 Subpart D)

And/Or Over the Counter Use ____X____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K073492